

EPN Comments on EPA's Scientific Integrity Policy Draft

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The [Environmental Protection Network](https://www.epn.org/) (EPN) harnesses the expertise of more than 600 former Environmental Protection Agency (EPA) career staff and confirmation-level appointees from Democratic and Republican administrations to provide the unique perspective of former regulators and scientists with decades of historical knowledge and subject matter expertise.

We are writing to provide comments on EPA's draft Scientific Integrity Policy. EPN applauds EPA's leadership on scientific integrity and supports the agency's efforts to update its policy consistent with the Office Of Science and Technology Policy (OSTP) guidance. We support many of the comments from Climate Science Legal Defense Fund and offer the following from EPN.

Background and Core Values

The written statement in lines 57-60 is problematic because the Scientific Integrity Official (SIO) and Deputy SIOs (DSIOs) have no authority to investigate research misconduct. Order 3120.5 was last updated on March 18, 2006, and does not mention any role for the SIO or DSIOs. Should there be a concern of plagiarism by a contractor or grantee, it does not give the EPA SIO investigating a claim of plagiarism the authority to do so. In addition, under XI Roles and Responsibilities (lines 936-1005), there is no mention of the SIO or DSIO having a role in research misconduct or plagiarism.

We suggest the 2nd and 3rd sentences be replaced with the following: *The SIO and DSIO shall report any allegations of potential research misconduct to the OIG. The OIG may delegate its authority to the SIO or DSIOs when requesting assistance investigating allegations of research misconduct.*

Scientific Integrity and Scientific Integrity Official

Line 95 - The SIO also has a responsibility to create reports about information to support the review and evaluation of scientific integrity concerns. We suggest the following change: *"The SIO collects, protects, and reports information to..."*

Authorities

The OSTP model policy does not include the housekeeping rule as an authority to be used by the agencies. Other agencies do not seem to be referencing their housekeeping rules in the development of their Scientific Integrity Policies (SIPs). Mentioning the housekeeping rule could raise confusion with EPA's now withdrawn final rule on Strengthening Transparency in Regulatory Science rule. This rule was deemed illegal because it was similarly based upon the EPA housekeeping rule. We strongly suggest that mention of this authority be removed.

The EPA policy should explicitly establish the exceptions to the SIP. The OSTP model SI policy includes a section on exceptions, leaving it up to the agency to declare its exceptions. In consultation with the Office of

General Counsel (OGC) and DSIO's, we recommend the SIO consider the following exceptions: actions that are mandated or prohibited by existing regulations, for example, protections of PII and CBI, and actions that might interfere with an ongoing personnel, civil, or criminal lawsuit. We also suggest a statement be included, such as, "*This policy shall be implemented consistent with applicable laws.*"

Definitions for the Purposes of this Policy

We recommend defining inappropriate influence as a type of interference; an *attempt to influence the outcome or findings of a scientific product to promote a desired result that is inconsistent with the use of best available science.* The current definition does not distinguish interference from influence and causes confusion. Inappropriate influence is a type of interference that deserves a clear distinction and better definition.

Best Available Science

We recommend adding a definition of "best available science." The definition should include a statement that access to data underlying Best Available Science should be encouraged but limited to the guidelines existing at the time data were collected. We suggest using the TSCA definition of best available science¹.

Conflict of Interest

We suggest adding a clear statement that receiving a grant from EPA or another federal agency is not a conflict of interest and does not disqualify a scientist from serving on a peer review committee or advisory committee.

External Elicitation

On line 494, it says that external elicitation and peer consultation should not be substituted for external peer review. We recommend adding a definition for external elicitation and peer consultation that clearly makes this distinction.

Protecting Scientific Processes

Sections *j*, *k*, and *l* (lines 393-404) seem too proscriptive and could create higher burdens on the agency than needed or lead to challenges against scientific products.

We suggest deleting the 1st sentence of section *j*. There may well be multiple proper and appropriate methods or processes available, creating an opportunity for a challenge.

In section *k*, not all scientific facilities and testing activities are eligible for independent review by sanctioning bodies. We recommend the following text modification: "*Ensure appropriate independent review of Agency scientific facilities and testing activities . . .*"

Section *l* as written could prohibit EPA scientists from publishing manuscripts exploring the use of emerging laboratory methods and models. This language should be focused on laboratory methods and models used for policymaking purposes. We provide the following suggestion: "*For policymaking purposes, ensure appropriate instructions on the application of the methods or models . . . is used in Agency science-based policies.*"

¹ We suggest this definition: <https://www.law.cornell.edu/cfr/text/40/702.33>

Suggested Modifications to Protecting Scientific Processes

Scientific processes that are not included in this section but should be considered include: personal identifying information, confidential business information, and public access to EPA research data. We recommend removing the section *Peer Review* (lines 459-547) that has been carried over from the Peer Review Handbook and existing guidelines related to FACA committees. These sections need only inform the reader of the aspects of the SIO and DSIOs' roles with respect to peer review and FACA committees. This policy does not need to reestablish existing policy on peer review or FACA committees.

We suggest adding an element to *Other Science Review* (lines 554-557) that is currently missing – ensure that Agency scientists and clearance officials use established scientific clearance guidelines [or best practices] that are readily available on the EPA internet and made available to the public. These guidelines should establish the clearance chain and reasonable timelines for the clearance of scientific products. The document does not adequately address scientific clearance.

In *EPA Public Affairs Officials* (lines 1026-1041), we recommend describing the role of these officials to include the media training of scientists, as media officials should provide media training to scientists.

In *Annual Meeting* (lines 1115 – 1120), we think requiring the Administrator or Deputy Administrator to attend annual meetings is unreasonable, given the ever-changing calendar of these officials. Instead, we suggest hosting an annual meeting on scientific integrity that will include the SIO, DSIOs, and the Chief Scientist. The Administrator, Deputy Administrator, Assistant Administrators, or their designees will be invited and encouraged to attend.

Professional Development for Government Scientists

Agency scientists need sufficient resources to attend professional meetings. We recommend that you modify section *c* (lines 846-847) to the following: “*Encourage and enable, consistent with available, dedicated resources, presentation of research at professional meetings...*” (“and enable, consistent with available, dedicated resources” added).

Agency scientists need sufficient time and resources to participate in professional society committees and task forces. We recommend modification of section *e* (lines 851-852) to the following: “*Encourage and enable participation in committees, task forces, and other specialized bodies of professional societies...*” (“and enable” added).

Roles and Responsibilities

To build and maintain a culture of continuing professional development, it is important that managers and supervisors of government scientists model exemplary commitment to professional development. The OIG should be included. We recommend the addition of a list of roles and responsibilities for EPA's inspector general. The list should include developing a set of SIO-OIG coordination procedures that take into account the unique expertise and capabilities of each party and specifies what kinds of issues can be handled by each, either independently of or in coordination with one another. The roles and responsibilities list for the OIG should include: investigations of research misconduct, investigations of a loss of scientific integrity involving a political appointee, and delegations of authority to the SIO.

We suggest the addition of a new item following part *d* in Section 8, Managers and Supervisors, that is parallel to part *d* but pertains to supporting professional development of government scientists: “Lead by example in professional development through engagement with professional societies.”

Investigations of the Loss of Scientific Integrity

Scientific integrity policies should include provisions to assure the timely resolution of an allegation of a loss of scientific integrity. For instance, a decision to investigate an allegation could be required within 10 working days and a determination within another 45 working days, and the appeal process could be limited to 30 working days.

Timeline for establishing procedures: We recommend that the policy state, “Within XX days of finalization of this policy, the SIO will place on the Agency website a final version of procedures for responding to allegations of compromised scientific integrity that conforms with this policy and has been approved by the Committee and Agency leadership.”

On line 700, there may be a run-on section. The sentence that begins "Reflect..." seems to be about a new thought.

Scientific Integrity in Collective Bargaining Agreements

Finally, EPN suggests the EPA Scientific Integrity policy be included in EPA Collective Bargaining Agreements with its Unions, as well as contract and grant agreements, to reinforce everyone's responsibilities to adhere to this SIP and ensure scientific integrity in EPA research and policymaking.